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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,283	05/04/2006	Tetsuji Yamaoka	18900-004/US1 200640/US	2757
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MINNEAPOLIS, MN 55440-1022				
EXAMINER				
POPA, ILEANA				
ART UNIT		PAPER NUMBER		
1633				
NOTIFICATION DATE		DELIVERY MODE		
08/19/2011		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

### Office Action Summary

**Application No.**

10/578,283

**Applicant(s)**

YAMACKA ET AL.

**Examiner**

ILEANA POPA

**Art Unit**

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 May 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 7-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 7-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Claims 2-6 have been cancelled. Claims 1, 7, 10 and 11 have been amended.  
Claims 1 and 7-11 are pending and under examination.

2. All rejections pertaining to claims 2-6 are moot because the applicant cancelled the claims in the reply filed on 05/26/2011.

The rejection of claims 1 and 7-11 under 35 U.S.C. 103(a) as being unpatentable over Kurisawa et al. (J Control Release, 2000, 68: 1-8), in view of both Fajac et al. (Glycoconjugate Journal, 2001, 18: 723-729) and Aoyagi et al. (J Biomater Sci Polymer Edn, 2000, 11: 101-110) is withdrawn in response to the amendments to the claims filed on 05/26/2011.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1 and 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raku et al. (Journal of Applied Polymer Science, 2001, 80: 384-387), in view of both Kurisawa et al. (J Control Release, 2000, 68: 1-8, of record) and Uludag et al. (Biotechnol Bioeng, 2001, 73: 510-521).

Raku et al. teach a temperature-responsive polymer copolymer of N-isopropylacrylamide (i.e., monomer A having a structure according to formula IV) and vinyladipoyl glucose (i.e., monomer B having a structure according to formula III), wherein the copolymer could have a molecular weight of 149,000 to 200,000 kDa (claims 1 and 8) (Abstract; p. 385, Scheme 1 and Table I). Although Raku et al. do not specifically teach transfection (claims 9-11), they do teach that the copolymer is suitable to deliver nucleic acids (p. 384, column 2, last paragraph; p. 385, column 1, first full paragraph; p. 386, column 2), and thus it would have been obvious to one of skill in the art to use their copolymer to introduce nucleic acids into cells.

Raku et al. do not teach a hydrophobic monomer having a structure according to formula V (claim 1). However, modifying the copolymer of Raku et al. by introducing a third, hydrophobic monomer is suggested by the prior art. For example, Kurisawa et al. teach that transfection efficiency is increased by incorporating butylmetacrylate into temperature-responsive nucleic acid carriers (p. 1; p. 2, paragraph bridging columns 1 and 2; p. 7, column 1, last paragraph). It would have been obvious to one of skill in the art, at the time the invention was made, to modify the polymer of Raku et al. according to the teachings of Kurisawa et al., with a reasonable expectation of success. One of skill in the art would have been motivated to do so in order to increase the transfection efficiency. One of skill in the art would have reasonably expected to be successful in doing so because the prior art teaches the successful enhancement of transfection efficiency by introducing hydrophobic groups into nucleic acid carriers. It is noted that, by doing such one of skill in the art would have obtained a copolymer wherein monomer

C is buthylmetacrylate, i.e., having a structure according to formula V except that  $R_9$  is butyl (i.e., it an alkyl chain with 4 and not 5 to 30 carbon atoms). However, using  $R_9$  with longer alkyl chains is suggested by the prior art. For example, Uludag et al. teach that the temperature at which the transition from the soluble to the insoluble form occurs can be adjusted by varying the alkyl chain length, wherein using longer chains (such as those comprising 6 and 12 carbon atoms) decreases the transition temperature and provides better controlled release under physiological conditions (Abstract; p. 511, column 1, first full paragraph; paragraph bridging p. 513 and 514; p. 515, column 1; p. 520, column 2). It would have been obvious to one of skill in the art, at the time the invention was made, to modify the copolymer of Raku et al. and Kurisawa et al. by varying the alkyl length of the  $R_9$  group with the purpose of optimizing the transition temperature and the nucleic acid release from the polymer according to the needs. With respect to claim 7, Uludag et al. teach that the transition temperature could also be influenced by the amount of incorporated monomer C (Abstract; p. 518, Table in Fig. 6); thus one of skill in the art would have found it obvious to also vary the amount of monomer C with the purpose optimizing the results.

Thus, the claimed invention was *prima facie* obvious at the time it was made.

### ***Conclusion***

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILEANA POPA whose telephone number is (571)272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ileana Popa/  
Primary Examiner, Art Unit 1633